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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/878,908	06/19/97	LAUTERJUNG	09114/005001

QM31/0713

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EXAMINER	
PREBILIC,P	
ART UNIT	**PAPER NUMBER**
3738	

DATE MAILED: 07/13/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
08/878,908	Lauterjung
Examiner: Prebilic	Group Art Unit: 3738

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Response

A SHORTENED STATUTORY PERIOD FOR RESPONSE IS SET TO EXPIRE Three (3) MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a response be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for response is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to respond within the set or extended period for response will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☒ Responsive to communication(s) filed on June 1, 1998.

☒ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☒ Claim(s) 1-36, and 47-52 is/are pending in the application.

Of the above claim(s) 29-31 and 50-62 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-28, 32-36, and 47-49 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been ☒ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____.

Attachment(s)

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 6

☐ Interview Summary, PTO-413

☒ Notice of References Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Other _____

Office Action Summary

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-36, and 47-49, drawn to the prosthesis, classified in class 623, subclass 1.

II. Claims 37-47, drawn to a method of securing a prosthesis, classified in class 623, subclass 1.

The inventions are distinct, each from the other because of the following reasons: Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the prosthesis could be used in a materially different process of use such as in the repair of a synthetic tube inside an extracorporeal blood treatment device.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

During a telephone conversation with Timothy Trop on January 13, 1998 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-36 and 47-49. **Affirmation of this election must be made by applicant in responding to this Office action.** Claims 37-46 and 50-51 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Acknowledgment is made of applicant's claim for foreign priority based on an applications filed in 196 24 642.3 and 196 33 588.4 on June 20, 1996 and August 20, 1996. It is noted, however, that applicant has not filed a certified copy of the applications as required by 35 U.S.C. 119(b).

Claims 1, 3, 6, 7, 9, 10, 11, 19, 22, 28, 29, 32, 33, and 35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In re claim 1, the claim scope is considered indefinite because it is based upon the size of a body passage of unknown size and is based upon how the device is intended to be used. For that reason, it is unclear how the body passage would modify the scope of the claim.

In re claims 3, 6, 7, 11, 19, 28, 29, and 32-35, the use of "including" is considered improper because components of these elements have already been set forth in earlier claims; therefore, the Examiner suggests changing "including" to ----further including---- in order to overcome this objection.

In re claim 9, line 2, it is unclear whether "a fabric graft" is related to the "graft" set forth in claim 7 from which this claim depends.

In re claim 10, it appears that the claim language is including a body passage as part of the invented device.

In re claim 22, lines 2-3, "the undeformed diameter" lacks antecedence.

In re claim 29, it is unclear how the prosthesis fits into the apparatus as claimed because there is no interrelationship set forth; i.e. it seems that the ring and graft are part of the prosthesis, and outside the scope of the claim preamble.

In re claim 32, there is no positive interrelationship of the first and second prosthesis sections.

In re claim 33, it is unclear which spring element is attached to the second prosthesis portion.

In re claim 35, lines 6-8, it is unclear which spring elements are attached to which tubular grafts.

The information disclosure statement filed September 15, 1997 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information referred to therein has not been considered. Specifically, a concise explanation or translation was not made for the foreign language references, and thus, they have been struck from the enclosed PTO-1449.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 47-49 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Quijano et al (US 5,500,014); see the entire document.

Claims 1-3, 6, 10, 12, 13, 16, 17, 19-23, 26, and 28-31 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Inoue (US 5,290,305); see the entire document.

Claims 1-4, 6, 12, 16, and 17 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Polansky (US 3,304,557); see the entire document.

Claims 1-6, 10, 12, 13, 16, 17, 19-26, 28, 29, 30, and 31 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Inoue (US 5,693,089); see the entire document.

Claims 1, 7, 8, 9, 11-15, and 18-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Taheri (US 5,617,878); see the entire document, particularly Figures 10-12.

With regard to claim 8 specifically, DACRON, by definition, is a fiber so the graft (12) is made of fibers to form a fabric; see Col. 3, lines 28-35.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 18 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taheri (US 5,617,878) alone. Taheri meets the claim language but teaches the use of a spring element on all free ends instead of only one free end as claimed. However, the Examiner posits that the use of a spring element on only one end, particularly the upstream side, would have been considered obvious to one of ordinary skill absent some showing of unobviousness.

Claims 7-9, 14, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Inoue (US 5,290,305) or Inoue (US 5,693,089) in view of Porter (US 5,064,435).
Inoue (both patents) meet the claim language except for the tapered or larger end of the graft as claimed. However, Porter teaches that it has been known to taper the ends of similar devices; see the figures thereof. Hence, it is the Examiner's position that it would have been obvious to taper the free ends of the graft of Inoue in order to improve the hold of the device to the vessel wall.

Claims 32-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Porter (US 5,064,435) in view of Inoue (US 5,290,305). Porter meets the claim language except for the tubular graft as claimed; see the entire document. However, Inoue teaches that it have been known to line similar self-expanding stents with grafts materials. Hence, it is the Examiner's position that it would have been obvious to surround the stents of Porter with graft material as taught by Inoue in order to prevent blood leakage in usages where leakage is harmful to the patient's health.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Prebilic whose telephone number is (703) 308-2905. The examiner normally be reached on Monday-Thursday from 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Weiss, can be reached on (703) 308-2702. The fax phone number for this Group is (703) 305-3590.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0858.

Paul Prebilic
Primary Examiner
Art Unit 3308